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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: P. Billing-Medel, *et al.*

Serial No.: 09/049,696

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For: REAGENTS AND METHODS USEFUL FOR DETECTING DISEASES OF THE GASTROINTESTINAL TRACT

Examiner: J. Kerr

Group Art Unit: 1633

Attorney Docket No.: 6067.US.P1

Date: October 29, 2001

**Certificate of Mailing under 37 CFR §1.8(a):**
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as First Class Mail addressed to:

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Wanda E. Smith 10/30/01
Wanda E. Smith Date

## DECLARATION OF DR. PHILIP HEMKEN UNDER 37 C.F.R 1.132

Box RCE
Assistant Commissioner of Patents
Washington, D.C. 20231

Dear Sir:

I, the undersigned, declare as follows:

1. I am one skilled in the art of cancer diagnostics. I have a Ph.D. in Molecular, Cellular and Developmental Biology from Iowa State University. I have a M.A. in Biotechnology from Washington University in St. Louis and I further have a B.S. in Microbiology from Iowa State University.

2. I was a Postdoctoral Fellow in the Laboratory of Dr. Andrei Mirzabekov at Argonne National Laboratory.

3. I have four years of research and development experience in the cancer diagnostic industry. Much of my work has involved the discovery and validation of novel cancer markers to improve the accuracy of diagnosing the onset of cancer. (See Curriculum Vitae - Exhibit A).

4. I have read and am familiar with the Patent Office Action dated January 31, 2001 and the Advisory Action of August 8, 2001; and with the rejection under 35 U.S.C. 101 applied against the instant application.

5. Exhibit B was generated as follows: Using CN as an example, equivalent amounts of total RNA from 20 different colon normal samples were combined and mRNA was purified from the pool. This mRNA pool represents the sample CN.

6. The normal and tumor tissues used for expression array analysis are listed in Table 1. The mRNA from the tumor and normal tissues were sent to Incyte Genomics where the cDNA was synthesized from the mRNA.

7. The cDNA from both the normal and tumor samples, were labeled with fluorescent dyes Cy3 or Cy5, mixed together and hybridized to human GEM 1-4 cDNA microarray chips (Incyte Genomics). The results are reported as the fold difference expression of CS194 (Incyte microarray clone ID# 1628788) hybridized with normal and tumor sample pools (see Figure 1).

8. As evidenced, CS194 expression is 2.3 fold higher in the colon tumor tissue pool compared to the colon normal tissue pool (see Figure 1).

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under § 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issued thereon.

_____ _____

Philip Hemken, PhD. Date